

Percutaneous transvenous mitral commissurotomy: with or without heparin? A randomised double blind study

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Abstract

Background: Percutaneous transvenous mitral commissurotomy (PTMC) is an alternative approach to open heart surgery in patients with symptomatic mitral stenosis (MS).

Aim: To compare the outcome of performing PTMC with or without heparin administration.

Methods: In this randomised clinical trial, 480 patients with symptomatic MS were randomly allocated to one of two groups, with or without heparin administration as part of the procedure. Echocardiographic and clinical outcomes of PTMC assessed before the procedure, during hospitalisation, and after the one-month follow-up, were compared between the two groups.

Results: Baseline demographic and clinical characteristics were similar in the 240 patients with heparin administration (the Hep [+] group) and the 240 patients without heparin administration (the Hep [–] group) during the procedure. In the whole study group mitral valve area (MVA) was $0.94 \pm 0.03 \text{ cm}^2$ prior to PTMC, and increased to $1.85 \pm 0.06 \text{ cm}^2$ after the procedure ($p = 0.0001$). The mean increase in MVA was $0.85 \pm 0.27 \text{ cm}^2$ in the Hep (+) group and $0.88 \pm 0.2 \text{ cm}^2$ in the Hep (–) group (NS). During the procedure, or immediately after PTMC, embolic events were recorded in two (0.83%) Hep (+) patients and one (0.42%) Hep (–) patient (NS). The frequency of haematoma at puncture site (three [1.25%] Hep [+] vs two [0.83%] Hep [–]), and the need for urgent surgery (two [0.83%] Hep [+] vs five [2.1%] Hep [–]), were similar in both groups. There were no embolic events after discharge or during the one month follow-up period.

Conclusions: Our study revealed that in high volume centres and in selected patients without left atrial thrombus, heparin administration during PTMC is not associated with any additional protective effect against embolic events during short-term follow-up.

Key words: mitral stenosis, percutaneous transvenous mitral commissurotomy, heparin, complications

Kardiol Pol 2011; 69, 5: 445–450

INTRODUCTION

Percutaneous transvenous mitral commissurotomy (PTMC) has been used as an alternative to surgical mitral commissurotomy in patients with symptomatic mitral stenosis (MS) since 1984 [1]. The PTMC produces significant changes in mitral valve morphology and improvement in leaflets mobility [2]. In order to avoid thrombus formation and thromboembolism due to in-

strumentation, anticoagulation with heparin has been usually used [3]. However, anticoagulant therapy may enhance the incidence of bleeding complications. Cardiac tamponade (0–9%) and haemopericardium (0.5–12%) are two previously reported complications of PTMC [4–6].

There is a paucity of information regarding the effects of performing PTMC without heparin on the rate of thrombo-

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Received: 05.09.2010 Accepted: 26.01.2011

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embolic events. Abraham et al. [7] investigated 629 patients with rheumatic MS in normal sinus rhythm (SR) who underwent PTMC without administration of heparin by the standard Inoue balloon technique after excluding left atrial (LA) clot, and found no incidence of embolism either immediately post-PTMC or during a follow-up period of three months.

Other studies have investigated only patients with MS and SR, excluding patients with atrial fibrillation (AF). However, AF is frequently associated with MS and is considered to be an unfavourable factor in terms of long-term prognosis [8, 9].

It is well known that the incidence of serious complications such as tamponade is closely related to operator experience [10]. Considering the reduced prevalence of rheumatic fever and valvular heart disease, even in developing countries [11], it might be expected that the number of high volume centres and experienced operators will continuously decline. This study aimed to compare the outcome of performing PTMC with or without heparin in MS patients with SR or AF.

METHODS

This double-blind randomised clinical trial was conducted with the approval of the Scientific and Ethical Review Board of Tabriz University of Medical Sciences. Four hundred and eighty consecutive patients with MS referred to our institution between January 2004 and December 2008 were enrolled in the study. Only symptomatic patients with isolated MS with a mitral valve area (MVA) ≤ 1.5 cm² or with less than moderate mitral regurgitation (MR) and who signed an informed consent form, were included in the study. Pregnant women, patients with chronic renal failure, those with LA thrombus in transoesophageal echocardiography (TEE), interatrial septum thickness > 4 mm, a recent thromboembolic event (in the three months prior to the procedure), or those needing simultaneous coronary angioplasty, were all excluded from the study.

The patients eligible for PTMC who met the inclusion and exclusion criteria were randomly assigned 1:1 to undergo PTMC with heparin injection (group Hep [+]) or without heparin injection (group Hep [–]) according to a computer-generated random series of numbers at the time of procedure. Trained nurses injected 4,000 IU of heparin, or the same amount of normal saline, intravenously at the beginning of the procedure while patients and interventionists were blinded to group assignment.

Using a GE Vivid 7 ultrasound machine, transthoracic echocardiography was performed the day before, and 24–48 h after, PTMC. The TEE was done the day before the procedure. Data regarding MVA, LA size, MR, MV score based on Wilkins classification [12] and severity of MR was recorded. Next, standard catheterisation of the left and right heart chambers and left ventriculography as well as aortography were performed; the decision for simultaneous coronary angiography was based on the AHA/ACC guidelines [13]. Fluid filled

catheters were used to record LA, ventricular and pulmonary artery pressures. The original classification scheme devised by Sellers et al. [14] was used to classify the severity of MR.

Using the Inoue balloon, four experienced operators performed all the PTMC procedures via a right femoral approach according to the technique previously described by Inoue et al. [15]. All the stages of the interventional procedure were similar in both groups. For safety reasons, considering the importance of possible thrombus formation in left heart chambers, we decided to consider the time limit of 10 min arbitrarily as a cut-off point for wire presence or balloon manoeuvres in the left chambers. Beyond this so-called 'wire time limit' the patient was excluded from the study.

During the procedure and immediately after PTMC, during hospitalisation, and up to one month after the procedure, patients were followed for possible symptoms or signs of peripheral embolisation and also for possible complications at the vascular puncture site. Significant haematoma was defined as haematoma with the largest diameter > 5 cm. The patients were examined immediately after the procedure and again after 24 h for the presence of a haematoma. Control echocardiography was performed the day after PTMC in all patients without knowing which group they had been assigned to.

For each subject, data were collected regarding age, gender, cardiac rhythm, mean LA and ventricular pressure, MVA before and after the procedure, pre- and post-PTMC trans-mitral pressure gradient, new or worsened MR, echocardiographic MV score and mean pulmonary artery pressure. We also recorded the time from first sheath insertion to last catheter or balloon removal as total procedural time.

Statistical analysis

Clinical, echocardiographic and haemodynamic variables were analysed using SPSS (statistical software ver. 13 for Windows, SPSS Inc., Chicago, IL, USA). Continuous variables are presented as mean $\pm$ SD. To compare quantitative variables between two groups, we used unpaired t-test. The χ^2 analysis or Fisher test were applied to compare qualitative variables between two groups. Continuous variables, before and after the procedure, were compared using a paired student t-test. A p value < 0.05 was considered statistically significant.

RESULTS

Excluding seven patients who required more than 10 min for balloon manoeuvres in the left heart, and four subjects in whom the first attempt at septostomy (three cases) or MV (one case) engagement failed, 480 patients with the symptoms of MS were finally enrolled in our study. These 480 patients were allocated randomly into two study groups: the Hep (+) group (240 subjects) and the Hep (–) group (240 subjects).

Table 1. Baseline demographic, echocardiographic, haemodynamic and procedural characteristics of the two groups

	Total (n = 480)	With heparin (n = 240)	Without heparin (n = 240)	P
Age [years]	39.5 ± 12.3	40.3 ± 12.1	38.6 ± 12.5	0.13
Female	410 (85.4%)	210 (87.5%)	200 (83.3%)	0.24
Basal MVA [cm ²]	0.94 ± 0.3	0.93 ± 0.27	0.95 ± 0.3	0.44
Mitral valve score ≥ 10	87 (18.1%)	52 (21.7%)	35 (14.6%)	0.57
LA dimension ≥ 6 [cm]	175 (36.5%)	96 (40%)	79 (33%)	0.12
Increase in MVA [cm ²]	0.87 ± 0.17	0.85 ± 0.027	0.88 ± 0.2	0.17
Atrial fibrillation	146 (30.4%)	82 (34.2%)	64 (26.7%)	0.10
Mean PAP [mm Hg]	47.4 ± 16.2	48.9 ± 18.7	46.2 ± 13.6	0.07
Mean TMVG [mm Hg]	14.1 ± 6.7	14.6 ± 7.3	13.5 ± 6.2	0.08
No MR	348 (72.5%)	168 (70%)	180 (75%)	
1+ MR	88 (18.3%)	50 (20.8%)	38 (15.8%)	0.55
2+ MR	42 (8.75%)	22 (9.17%)	20 (8.3%)	
3+ MR	2 (0.42%)	0	2 (0.83%)	
Wire time [min]	6.2 ± 2.2	6.5 ± 1.9	5.9 ± 2.5	0.003
Need for CAG	158 (32.9%)	86 (35.8%)	72 (30%)	0.21
Procedure duration [min]	37.6 ± 20.6	39.8 ± 21.4	34.5 ± 19.8	0.02

MVA — mitral valve area; LA — left atrium; AF — atrial fibrillation; PAP — pulmonary artery pressure; TMVG — trans-mitral valve gradient; MR — mitral regurgitation; CAG — coronary angiography

Baseline demographic, echocardiographic and angiographic data of each group are compared in Table 1. Briefly, the mean age of participants, frequency of female patients, MV score ≥ 10, mean LA size, mean pulmonary artery pressure or transmitral valve gradient and the percentage of patients who required coronary angiography were all similar. Wire time and procedure time were significantly longer in the Hep (+) group.

The MVA was 0.94 ± 0.03 cm² prior to PTMC, and increased to 1.85 ± 0.06 cm² after the procedure ($p = 0.0001$). The mean increase in MVA was similar in both groups. More than 2+ MR according to Sellers classification was present in two (0.42%) patients before the procedure and this increased to 11 (2.3%) patients after PTMC ($p = 0.02$). However, the distribution of severity of MR was similar in both groups.

Left atrial wall injury did not occur in any patients during the procedure. There was no evidence of newly developed or worsened pericardial effusion after PTMC. There were no patients with significant bleeding needing transfusion. Three patients suffered from peripheral emboli (two in the Hep (+) group and one in the Hep (–) group) which presented as transient cerebral ischaemic attack in all cases, with full recovery during the index hospitalisation (Table 2). Two of these three patients were in AF during the procedure. The frequency of significant haematoma and the need for MV surgery during the same hospitalisation was not different between the two groups. The course of one-month follow-up was uneventful in both groups.

DISCUSSION

This study indicates that PTMC is a safe procedure, regardless of the heparin usage. Similar results were presented by Abraham et al. [7] who reported no cases of thromboembolism during a three-month follow-up period after performing PTMC without heparin. Although the sample size was higher (629 subjects) compared to our population (480 subjects), that study was conducted in a more selective population. They enrolled only patients who had SR. Thus, their findings may not be applicable to all patients with MS, because a significant proportion of these patients have associated AF [8, 9].

Atrial fibrillation has been reported to be a predictor of poor outcome after PTMC in patients with MS [16]. A study by Srimahachota et al. [16] indicated that patients with MS and AF had a larger LA and lower pre-PTMC pulmonary artery pressure than the patients who had MS and SR. Moreover, it has been shown that patients with SR have a more favourable pulmonary artery and LA pressure reduction than patients with AF after PTMC.

The risk of thromboembolic events, which was one of the essential outcome measures in our study, has been reported in the literature to be seven times greater in those with AF compared to their counterparts with SR [17]. Most of the studies in the field of mitral valvuloplasty have been conducted in young populations [2, 18]. Similarly, the mean age of the subjects in the study by Abraham et al. [7] (29.5 ± 9.9 years) was lower than the mean age of the subjects in our study (39.5 ± 12.3 years). The higher mean age of our patients

Table 2. Outcome of PTMC in the two groups with and without heparin administration

	Total (n = 480)	With heparin (n = 240)	Without heparin (n = 240)	P
Increase in MVA	0.87 ± 0.17	0.85 ± 0.27	0.88 ± 0.2	0.17
No MR	294 (61.3%)	149 (62.1%)	145 (60.4%)	0.60
1+ MR	119 (24.8%)	63 (26.3%)	56 (23.3%)	
2+ MR	56 (11.7%)	27 (11.3%)	29 (12.1%)	
3+ MR	4 (0.83%)	1 (0.42%)	3 (1.3%)	
4+ MR	7 (1.46%)	4 (1.7%)	3 (1.3%)	
Significant haematoma	5 (1.04%)	3 (1.25%)	2 (0.83%)	0.37
Embolic event	3 (0.63%)	2 (0.83%)	1 (0.42%)	0.9999
Need for surgery	7 (1.46%)	2 (0.83%)	5 (2.1%)	0.45
Tamponade	0	0	0	0.9999

PTMC — percutaneous transvenous mitral commissurotomy; rest abbreviations as in Table 1

compared to the study by Abraham et al. [7] may be also explained by the findings of Srimahachota et al. [16], who showed that patients with concurrent MS and AF are older than patients with MS and SR. Rajbhandari et al. [19] conducted a study including 200 patients who underwent PTMC, in which AF was present in 32% of subjects. Only one case of systemic embolisation and one case of deep vein thrombosis were reported, despite the use of heparin during the procedure.

In our study, patients with thrombus in LA appendage were excluded from the study. Srimannarayana et al. [20] tried to evaluate the prevalence of LA thrombus in patients with rheumatic MS with AF and to document the effects of long-term anticoagulation on clot dissolution. Among 490 patients, 33.2% had LA thrombus and only two of 17 patients who had LA thrombus had successful clot dissolution after long-term oral anticoagulation. Our policy for such patients is long-term anticoagulant therapy and repeat TEE at three-month intervals. We perform PTMC only after complete resolution of LA appendage clot, except for exceptional haemodynamically unstable patients with higher surgical risk. In a study by Silaruks et al. [21] a total of 75 patients with documented LA thrombus were followed for six to 34 months. The thrombus was completely resolved in 48 (64%) cases. They concluded that the smaller thrombus is associated with greater likelihood of thrombus resolution after receiving oral anticoagulant, and the enhanced possibility of performing a safe PTMC procedure.

In our study, three patients suffered from an embolic event. The frequency of this complication has been reported as between 0.3% and 3% with standard protocols using heparin during the procedure [22–27]. Considering our patients' relatively higher ages and the significant proportion of patients with AF, it seems that the rate of this complication in our

study was well within the range of published results with heparin administration.

To the best of our knowledge, there has been no study correlating the PTMC procedure time and frequency of thromboembolic events. The wire time was longer in the group with heparin injection, and the total procedure time also was increased in this group. This longer wire time, together with the slightly higher, albeit nonsignificant, rate of the need for coronary angiography in this group, may be responsible for longer total procedural time in this population of patients.

We followed our patients for only one month; this may be a study limitation. However, it could not be expected that complications or any outcomes related to intraprocedural heparin injection could affect mid-term or long-term outcome. In a study by Saeki et al. [28], long-term clinical and echocardiographic outcomes of patients treated with PTMC were evaluated and the six-year survival rate with freedom from thromboembolism was reported to be 91%.

Limitations of the study

For safety considerations, and according to our ethics committee recommendations, we excluded patients who needed more than 10 min for wire presence or balloon manoeuvres in left chambers. Due to the low number of such cases we could not evaluate the characteristics of this group. Larger studies with an intention to treat (10 min no heparin strategy) design are needed to evaluate this strategy.

CONCLUSIONS

In high volume centres with experienced operators and short procedural times, in selected patients without LA thrombus and less than 10 min wire and balloon manoeuvres in the left heart, heparin administration during the procedure is not associated with any additional protective effect against embolic events.

Conflict of interest: none declared

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Przezskórna, przezżylna komisurotomia mitralna: z heparyną czy bez heparyny? Randomizowane badanie metodą podwójnie ślepej próby

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Streszczenie

Wstęp: Przezskórna, przezżylna komisurotomia mitralna (PTMC) u pacjentów z objawową stenozą mitralną (MS) jest metodą alternatywną w stosunku do zabiegu kardiochirurgicznego na otwartym sercu.

Cel: Celem pracy było porównanie wyników leczenia metodą PTMC z zastosowaniem heparyny lub bez heparyny.

Metody: W ramach badania klinicznego 480 pacjentów z objawową MS przydzielono metodą randomizacji do grupy, w której podanie heparyny stanowiło element procedury, lub grupy, w której heparyny nie stosowano. Porównano dane echokardiograficzne i kliniczne w obu grupach przed procedurą, podczas hospitalizacji i w obserwacji miesięcznej.

Wyniki: Wyjściowe dane demograficzne i kliniczne nie różniły istotnie 240 pacjentów, u których podczas zabiegu zastosowano heparynę [grupa Hep (+)] od 240 pacjentów, u których jej nie użyto [grupa Hep (-)]. Powierzchnia zastawki mitralnej przed zabiegiem PTMC wynosiła $0,94 \pm 0,03 \text{ cm}^2$, a po zabiegu wzrosła do $1,85 \pm 0,06 \text{ cm}^2$ ($p = 0,0001$). Średni przyrost pola powierzchni zastawki wynosił $0,85 \pm 0,27 \text{ cm}^2$ w grupie Hep (+) oraz $0,88 \pm 0,2 \text{ cm}^2$ w grupie Hep (-) ($p = \text{NS}$). W czasie lub bezpośrednio po PTMC zanotowano 2 (0,83%) incydenty zatorowe w grupie Hep (+) oraz 1 (0,42%) w grupie Hep (-) ($p = \text{NS}$). Liczba krwaków w miejscu nakłucia naczynia [3 (1,25%) Hep (+) v. 2 (0,83%) Hep (-)] oraz konieczność pilnego wykonania zabiegu chirurgicznego [2 (0,83%) Hep (+) v. 5 (2,1%) Hep (-)] w obu grupach były podobne. Nie zaobserwowano incydentów zatorowych po wypisaniu pacjentów ani w miesięcznym okresie obserwacji.

Wnioski: Badanie wykazało, że w ośrodku wykonującym dużą liczbę zabiegów u wybranych osób bez skrzepliny w uszku lewego przedsionka podanie heparyny podczas PTMC nie przynosi żadnych dodatkowych korzyści w zakresie ochrony przed incydentami zatorowymi w obserwacji krótkoterminowej.

Słowa kluczowe: stenoza mitralna, przezskórna, przezżylna komisurotomia mitralna, heparyna, powikłania

Kardiologia 2011; 69, 5: 445–450

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Praca wpłynęła: 05.09.2010 r. Zaakceptowana do druku: 26.01.2011 r.